IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
EASTERN DIVISION

No. 4:13-CV-76-H

ROBERTA SPILKER, individually and as Executrix of the Estate of FRANKLIN J. SPILKER, JR., deceased,

Plaintiffs,

vs.

MEDTRONIC, INC., and MEDTRONIC CRYOCATH LP,

Defendants.

ORDER

This matter comes before the Court on the Motion of Defendants Medtronic, Inc. and Medtronic Cryocath LP for an order to file under seal Volume I of Medtronic's CryoCatheter System's Pre-Market Application ("PMA") (DE-76). The Court, having considered the motion, finds as follows:

1. Medtronic requests that the Court file under seal Docket Number 76, which is Exhibit A to Medtronic's Motion And Memorandum Of Law For A Court Determination That Volume 1 Of The CryoCatheter System's Pre-Market Approval Application Is Properly Designated As Highly Confidential.
2. This Highly Confidential document overcomes the presumption to access. The Seventh Circuit confirmed that "in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law." *Bausch v. Stryker Corp.*, 630 F.3d 546, 560 (2010). "The specifications of the FDA's premarket approval documents," the court further explained, "are confidential, and there is no public access to complete versions

of these documents." *Id.* The public "cannot gain access to that information without discovery." *Id.* The Freedom of Information Act specifically allows the FDA to withhold documents containing matters that are "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The FDA maintains the confidentiality of the CryoCatheter System's PMA Application because of the trade secrets contained in it. *See Judicial Watch, Inc. v. FDA*, 449 F.3d 141, 149 (D.C. Cir. 2006) (noting that if a drug manufacturer's competitor "could obtain all the data in the manufacturer's [application], it could utilize them in its own [application] without incurring the time, labor, risk, and expense involved in developing them independently").

3. Medtronic submitted Volume I of the PMA application to the FDA confidentially in order for Medtronic to obtain approval for its CryoCatheter System. This process necessarily requires Medtronic to submit its trade secrets and confidential data to the FDA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008) (noting that the PMA process requires a manufacturer to submit this detailed information to the FDA, which the FDA then reviews, spending an average of 1,200 hours on each submission). And the document is thus full of sensitive Medtronic trade secrets. The application contains data from various clinical studies conducted by Medtronic and others; Medtronic's conclusions and recommendations; detailed design specifications; detailed manufacturing specifications; and detailed marketing information. *See Reiter v. Zimmer, Inc.*, 897 F. Supp. 154, 157 (S.D.N.Y.1995) (noting that the PMA process "requires the applicant to submit 'extensive safety testing data and descriptions of manufacturing methods and materials'") (citations omitted); *In re Eli Lilly & Co., Prozac Products Liability Litigation*, 142 F.R.D. 454, 460 (S.D. Ind. 1992) (holding pharmaceutical company would suffer harm if the manufacturing process it has expended

time and money developing became known to competitors). "Applicants spend a great deal of resources to obtain data for" FDA approval of their product applications. *Judicial Watch, Inc.*, 449 F.3d at 149.

4. Alternatives to filing under seal are unavailable. To file publicly, Medtronic would be required to redact most of the document to hide its sensitive trade secrets, which is impractical. The only viable option is to file the entire document under seal.
5. Plaintiff has consented to Medtronic filing Volume I of the CryoCatheter System's PMA Application under seal.

NOW THEREFORE, IT IS ORDERED ADJUDGED AND DECREED that, for good cause shown, the Court finds that Defendants' Motion To File Under Seal The Highly Confidential Volume I To The Cryocatheter System's Pre-Market Application is GRANTED.

SO ORDERED, this the 13 day of April, 2015.

Robert B. Jones, Jr.
United States Magistrate Judge